



TEXAS STATE BOARD OF PHARMACY

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Oren M. Peacock Jr., R.Ph.
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March 15, 1999

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Dockets Management Branch (FHA-305-105)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Bill C. Pittman, R.Ph.
Treasurer
Austin

Gilbert Acuna, R.Ph.
Kingsville

RE: Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling

Wiki Erickson
Waco

Docket No. 98D-1266

Doyle E. High, R.Ph.
Haskell

COMMENTS

The staff of the Texas State Board of Pharmacy have reviewed the above referenced draft document and would like to make the following comments.

Susan H. Jacobson
El Paso

Ira Wayne McConnell, CPA
Houston

We strongly endorse the concept of placing the therapeutic equivalence code on stock containers of prescription drugs. However, there is one area of concern. You provide the following example:

Donna Burkett Rogers, R.Ph.
San Antonio

GROUCHOSE®
(Harpose Tablets, USP)

Gay Dodson, R.Ph.
Executive Director/Secretary
Austin

— mg
AB to CHICOSE®*

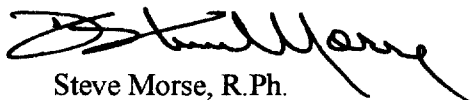
*Chicose® is a registered trademark of Marx Brother, Inc.

OR

This product is AB to CHICOSE®. Chicose® is a registered trademark of Marx Brothers Inc.

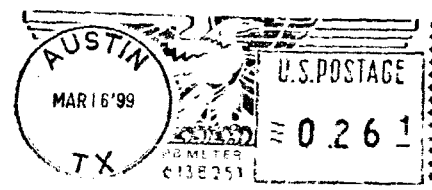
Our concern is with placing in any manner, a brand name (e.g., Chicose) on the label of a different drug product (e.g., Grouchose). Even with the precautions being taken, reduced type size, etc., merely placing the second drug name on the label could lead to dispensing errors by pharmacist who misread this bottle as containing the second drug (Chicose in your example).

Sincerely,


Steve Morse, R.Ph.
Director of Compliance

98D-1266

C3



HA-305-105)

